

- (a) contacting said test sample with at least one reagent polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, position 14-482 of SEQ ID NO:4 and degenerate codon equivalents thereof;
- (b) detecting a presence of the target polynucleotide in the test sample; and
- (c) correlating the presence of the target polynucleotide with the presence of breast cancer in the patient.

51. The method of claim 50, wherein said target polynucleotide is attached to a solid phase prior to performing step (a).

52. A method for diagnosing breast cancer in a patient by detecting an amplicon in a test sample taken from a patient, comprising:

- (a) obtaining the test sample from the patient;
- (b) performing reverse transcription with at least one first primer in order to produce cDNA;
- (c) amplifying the cDNA obtained from step (b) using sense and antisense primers to obtain an amplicon;
- (d) detecting a presence of the amplicon in the test sample; and
- (e) correlating the presence of the amplicon with breast cancer in the patient, wherein the primers utilized in steps (b) and (c) are selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, position 14-482 of SEQ ID NO:4 and degenerate codon equivalents thereof

53. The method of claim 52, wherein the test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

54. The method of claim 52, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

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55. A method of diagnosing breast cancer in a patient by detecting a target polynucleotide in a test sample taken from the patient, comprising:

(a) contacting the test sample with at least one first oligonucleotide as a sense primer and with at least one second oligonucleotide as an anti-sense primer and amplifying to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one third oligonucleotide to obtain a second stage reaction product, with the proviso that the at least one third oligonucleotide is located 3' to the first and second oligonucleotides utilized in step (a) and is complementary to said first stage reaction product;

(c) detecting said second stage reaction product as an indication of a presence of the target polynucleotide; and

(d) correlating the presence of the target polynucleotide with a presence of breast cancer in the patient, wherein the oligonucleotides utilized in steps (a) and (b) are selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, position 14-482 of SEQ ID NO:4 and degenerate codon equivalents thereof.

56. The method of claim 55, wherein the test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

57. The method of claim 55, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.

58. The method of claim 57, wherein said detectable label is reacted to a solid phase.

59. A test kit useful for detecting a target polynucleotide indicative of breast cancer in a test sample, the test kit comprising:

a container containing at least one polynucleotide encoding a mucin and selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, position 14-482 of SEQ ID NO:4 and degenerate codon equivalents thereof.

60. A purified polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3 and degenerate codon equivalents thereof.

61. The purified polynucleotide of claim 60, wherein said polynucleotide is produced by recombinant techniques.

62. The purified polynucleotide of claim 60, wherein said polynucleotide is produced by synthetic techniques.

63. A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host, wherein the nucleic acid sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, position 14-482 of SEQ ID NO:4 and degenerate codon equivalents thereof.

64. A cell transfected with the recombinant expression system of claim 63.

65. A composition of matter comprising a polynucleotide selected from the group consisting of:  
SEQ ID NO: 1, SEQ ID NO:3 and degenerate codon equivalents thereof.

66. The test kit of claim 59 further comprising:  
a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

67. A gene comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO:16 and degenerate codon equivalents thereof.

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Sub  
F1

Sub E1

Sub E1  
68. A gene comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and degenerate codon equivalents thereof.

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69. A method of detecting a presence of breast cancer in a patient by detecting a target polynucleotide in a test sample taken from the patient, comprising:

- (a) contacting the test sample with at least one reagent polynucleotide selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5 and degenerate codon equivalents thereof;
- (b) detecting a presence the target polynucleotide in the test sample; and
- (c) correlating the presence of the target polynucleotide with the presence of breast cancer in the patient.

#### REMARKS

Claims 11-16, 33, 38-39, 43-48 are rejected under 35 USC 102(a) in view of Adams et al. And Hillier et al. These claims have been cancelled. New claims 50- 69 do not include percent identity language, complement language or fragment language. Applicant respectfully submits that these claims are not anticipated by Adams et al. Or Hillier et al. New claims 50-69 are further clarified by "degenerate codon equivalents" language. The degeneracy of the genetic code is a concept that is well-known to those skilled in the art and is even discussed in section 2144.09 of the February 2000 revision of the Manual for Patent Examining Procedure as "the fact that most amino acids are specified by more than one nucleotide sequence or codon." Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-10, 35, 40-42 and 49 are rejected under 35 USC 112, first paragraph. The Examiner states that the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. These claims have been canceled. The Examiner states that the specification does not support an association of expression of mRNA to "breast disease".